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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/507,463	09/10/2004	David Selwood	GJE-6595	8237
23557 7590 05/31/2007 SALIWANCHIK LLOYD & SALIWANCHIK A PROFESSIONAL ASSOCIATION PO BOX 142950 GAINESVILLE, FL 32614-2950			EXAMINER DUTT, ADITI	
			ART UNIT 1649	PAPER NUMBER
			MAIL DATE 05/31/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/507,463	<b>Applicant(s)</b> SELWOOD ET AL.	
	<b>Examiner</b> Aditi Dutt	<b>Art Unit</b> 1649	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 March 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,7,13 and 14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,7,13 and 14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Status of Claims***

1. The amendment filed on 5 March 2007 has been entered into the record and has been fully considered. Claims 1 and 7, are amended. Claims 2-6, and 8-12 are canceled. New claims 13 and 14 are amended.
2. Claims 1, 7, 13 and 14, directed to a peptide or its fragment that retains NP-1 (neuropilin-1) antagonist activity and a pharmaceutical composition comprising the peptide, are being considered for examination in the instant application.
3. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicants response and withdrawn.
4. Applicant's arguments filed on 5 March 2007, have been fully considered. New grounds of objection and rejection are as follows:

### ***Response to Amendment***

#### **Withdrawn objections and/or rejections**

5. Upon consideration of the Applicant's amendment, all claim objections and rejections, not reiterated herein have been withdrawn, as overcome by cancellation and/or amendment of claims (5 March 2007).
6. Upon consideration of the amendment to claim 1 and the cancellation of claim 2, rejection of the claims 1 and 2 under 35 USC § 101 is withdrawn.

7. Upon consideration of the cancellation of claim 8, rejection of claim 8 under 35 USC § 112, second paragraph, is withdrawn.

Claim rejections/objections maintained/new grounds of rejection

35 U.S.C. 112-first paragraph- Scope of Enablement.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. The rejections of claims 1, 2, 7 and 8, are applied to the amended claims 1 and 7, and new claims 13 and 14, for reasons of record in the Office Action dated 30 October 2006.
9. Applicant argues that the claimed peptides are in bicyclic form, have four cysteine residues, and have at least 22 amino acids of SEQ ID NO: 2, and further adds that the peptides probably have a substantially similar activity as that of a neuropilin-1 (NP-1) antagonist. On account of the defined structural features combined with the functional characteristic of NP-1 antagonist activity, Applicant believes that there will only be a finite number of peptides with such structural and functional features, therefore, experimentation may simply be routine, not undue. Applicant has amended the claims to remove the reference to "pharmaceutical". Applicant cites case law to support this contention.
10. Applicant's arguments directed to the claimed invention have been fully considered but have been found to be persuasive in part. Since the reference to

“pharmaceutical” is removed, the portion of 35 U.S.C. 112, first paragraph rejection, directed to this reference is withdrawn. However, the claims still recite fragments of the claimed peptides. Even though the peptides are bicyclic, the fragments will result in an infinite number of sequences. Applicant only specifies the requirement of 4 cysteine residues in the bicyclic peptide. Applicant does not identify a particular peptide domain that needs to be preserved for NP-1 antagonist activity. Applicant’s contention that the peptides will have at least 22 out of 28 amino acids (implying about 78% homology), is not sufficient evidence of a conserved structure. Applicant has provided little or no guidance beyond the mere presentation of sequence data to enable one of ordinary skill in the art to determine, without undue experimentation, the positions in the peptide, which are tolerant to change, and the nature and extent of changes that can be made in these positions. Undue experimentation would be required of the skilled artisan to determine such. Specifically, proper analysis of the Wands factors was provided in the previous Office Action. Due to the large quantity of experimentation necessary to generate the infinite number of fragments of SEQ ID NO: 2 recited in the claims and screening such for NP-1 inhibiting activity; the lack of direction/guidance presented in the specification regarding the same; the complex nature of the invention; the state of the prior art which establishes the unpredictability of the effects of mutation on protein structure and function; and the breadth of the claims which fail to recite any structural or functional limitations

- undue experimentation would be required of the skilled artisan to make and/or use the claimed invention.

112, 1<sup>st</sup> paragraph, Written Description

11. The rejections of claims 1, 2, 7 and 8, are applied to the amended claims 1 and 7, and new claims 13 and 14, for reasons of record in the Office Action, dated 30 October 2006.
12. Applicants submit that the amended claims are directed to bicyclic form of peptides, having 4 cysteine residues, consisting of at least 22 of the 28 amino acids of SEQ ID NO: 2, and eliciting NP-1 antagonist activity. Applicants, therefore, conclude that the claimed peptides have a conserved structure associated with a function, thus fully comply with the written description requirement.
13. Applicant's arguments have been fully considered but have not been found to be persuasive. For reasons explained above, the brief description in the specification of one EG3287 peptide (SEQ ID NO: 2) is not adequate written description of an entire genus of functionally equivalent polypeptides, which incorporate all fragments of EG3287 peptide. Therefore, only the EG3287 peptide comprising the amino acid sequence of SEQ ID NO: 2, but not the full breadth of the claims meets the written description provision of 35 U.S.C. §112, first paragraph.

103(a)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. The rejections of claims 1, 2, 7 and 8, are applied to the amended claims 1 and 7, and new claims 13 and 14, for reasons of record in the Office Action, dated 30 October 2006.
15. Applicant argues that although Li teaches the sequence of the claimed peptide of SEQ D NO: 2, the reference does not teach the functional advantages of the peptide or its active fragments, viz. NP-1 antagonist activity. Similarly, Applicants add that Achen et al. do "not add any disclosure that would aid a person of skill in identifying the claimed peptide from the sequences taught by Li". Applicants further assert that "the cited art provides no teaching or suggestion of the specific advantageous bicyclic peptides", therefore, "the combination of Li and Achen does not render obvious the subject matter". Applicants thus believe the rejection should be withdrawn.
16. Applicant's arguments have been fully considered but have not been found to be persuasive. The peptide cited in the reference plays a role in preventing and treating tumors, besides having 100% identity with the claimed peptide. As the functions are similar to the claimed peptide, the advantages as

claimed, are inherent to the peptide of the reference. Thus, claims 1, 7, 13 and 14 as a whole is *prima facie* obvious over the teachings of Li et al and Achen et al, and stay rejected.

### ***Status of Claims***

17. No claims are allowed.
18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).
19. A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.
20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aditi Dutt whose telephone number is (571)



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272-9037. The examiner can normally be reached on Monday through Friday, 9:00 a.m. to 5:00 p.m.

21. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.
22. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov/>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AD  
22 May 2007

  
JANET L. ANDRES  
SUPERVISORY PATENT EXAMINER